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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,823	07/22/2003	Alastair McIndoe Hodges	LFSCAN.60C2C2	6567

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EXAMINER	
NOGUEROLA, ALEXANDER STEPHAN	
ART UNIT	**PAPER NUMBER**
1753	

DATE MAILED: 07/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/624,823	HODGES ET AL.	
	Examiner	Art Unit	
	ALEX NOGUEROLA	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-6 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-6 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 27 July 2003 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 08/981,385.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 02/20/2002.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: See Continuation Sheet.

Continuation of Attachment(s) 6). Other: IDS of 9/20. 2004, IDS of 3/18,2005.

DETAILED ACTION

Information Disclosure Statement

1. Applicants are requested to provide copies of the following documents that are cited on the Information Disclosure Statement of February 20, 2002 ("IDS"), but were not found in the parent applications

SU 1351-627 A,

AU A 54873/94,

AU A 31042/93,

JP 466112 A,

JP 3167464,

JP 6222874,

DE 3103-464,

DE 3103464 A1, and

all of the documents cited in « Other Documents », which is on sheets 4-5 of the IDS.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the combination of claims 24, 31, 57, and 58 of U.S. Patent No. 6,284,125 B! in view of Diebold et al. (US 5,437,999) ("Diebold"). The combination claims 24, 25, 31, and 58 of U.S. Patent No. 6,284,125 B! meets all of the limitations of claim 1 of the instant application except for the requirement of a spacer made of non-conductive polymer interposed between the working electrode and the counter electrode. Diebold discloses a spacer made of non-conductive polymer interposed between a working electrode and a counter electrode. See Figure 5 and col. 7:55-57. It would have been obvious to use a spacer made of non-conductive polymer in the invention of claim 1 of the instant application because such a spacer will allow the working electrode and the counter electrode to be positioned in a non-

coplanar arrangement, yet be closely spaced and have a small, well-defined effective cell volume. Another benefit of the spacer of Diebold is that the cell volume is in the shape of capillary that spontaneously draws in sample and prevents contamination of the meter. See col. 8:45-60. The spacer is non-conductive to, of course, avoid short-circuiting of the working and counter electrodes.

4. Claim 2 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the combination of claims 24, 32, 57, and 58 of U.S. Patent No. 6,284,125 B! in view of Diebold et al. (US 5,437,999) ("Diebold"). Claim 1, from which claim 2 depends, has been addressed above.

Claim 32 of U.S. Patent No. 6,284,125 B! meets the additional limitation of claim 2 of the instant application.

5. Claim 3 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the combination of claims 24, 32, 34, 57, and 58 of U.S. Patent No. 6,284,125 B! in view of Diebold et al. (US 5,437,999) ("Diebold"). Claim 2, from which claim 3 depends, has been addressed above.

Claim 34 of U.S. Patent No. 6,284,125 B! meets the additional limitation of claim 3 of the instant application.

6. Claim 4 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the combination of claims 24, 32, 34, 57, and 58 of U.S. Patent No. 6,284,125 B! in view of Diebold et al. (US 5,437,999) ("Diebold"). Claim 3, from which claim 4 depends, has been addressed above.

Claim 34 of U.S. Patent No. 6,284,125 B! meets the additional limitation of claim 4 of the instant application.

7. Claim 5 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the combination of claims 24, 29, 32, 34, 38, 57, and 58 of U.S. Patent No. 6,284,125 B! in view of Diebold et al. (US 5,437,999) ("Diebold"). Claim 4, from which claim 5 depends, has been addressed above.

Claims 29 and 38 of U.S. Patent No. 6,284,125 B! meet the additional limitation of claim 5 of the instant application.

8. Claim 6 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the combination of claims 24, 31, 57, and 58 of U.S. Patent No. 6,284,125 B! in view of Diebold et al. (US 5,437,999) ("Diebold"). Claim 1, from which claim 6 depends, has been addressed above. If the spacer of

Diebold is used than the spacer and the electrodes will define the effective volume of the hollow electrochemical cell. See Figure 5 of Diebold. As discussed in the rejection of claim 1, one benefit of the spacer of Diebold is that it the cell volume is in the form a capillary channel that spontaneously draws in sample.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1-4 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diebold et al. (US 5,437,999) in view of Straus et al. (US 5,089,320) ("Straus").

Addressing claim 1, Diebold discloses a hollow electrochemical cell for measuring a concentration of

glucose in a blood sample, the hollow cell comprising

(a) at least one working electrode (11);

(b) at least one counter or counter/reference electrode (48), wherein the working electrode and the counter or counter/ reference electrode are not coplanar (Figure 5) and a separated by a very small distance (implied by Figure 5 and related passages, which disclose thin layers);

(c) a spacer (43) interposed between the working electrode and the counter electrode or counter/reference electrode (Figure 5), where the spacer comprises a non-conductive polymeric material (col. 7:14-18 and col. 7:55-57), and wherein the hollow

electrochemical cell has a small effective volume (implied by col. 8:45-50, which discloses that the cell is part of a capillary space).

Diebold does not mention (1) whether the working electrode in the embodiment of Figure 5 is non-metal, (2) having the working electrode and the counter or counter/reference electrode spaced from about 20 microns to about 200 microns, and (3) having the effective cell volume be less than 1.5 microliters

As for having the working electrode be non-metal, Diebold does broadly disclose providing a non-metal working electrode. Diebold states, "A working, counter, or reface electrode element may be produced in accordance with the present invention as shown in Fig. 1. Electrically conducting material **1** (e.g., a noble metal or carbon) is vacuum sputtered or evaporatively deposited onto thin support material **2** ..." [emphasis added]. See col. 3:50-54. the decision as to whether to use a metal working electrode or a non-metal working electrode was within the skill of one with ordinary skill in the art at the time of the invention. The major factors that would be considered are cost of manufacturing and retail price of the electrochemical cell (noble metals, such as gold and platinum are more expensive than carbon) and desired measurement accuracy.

As for the working electrode and the counter or counter/reference electrode spaced from about 20 microns to about 200 microns, Diebold discloses using a MYLAR™ film as a spacer (col. 7:14-18 and col. 7:55-57), but does not disclose the thickness. Diebold also discloses using MYLAR™ film of approximately 10 mil (254 microns) thickness as an electrode support (col. 5: 62-67), which if not the same MYLAR™ film as used for her spacer is certainly an obvious variant. As shown by

Straus, at the time of the invention MYLAR™ film of only 12.2 microns in thickness was commercially available. See col. 4:53-56. Barring evidence to the contrary, such as unexpected results Applicants' claimed distance between the working electrode and the counter or counter/reference electrode of from about 20 microns to about 200 microns is just a matter of scaling the spacer of Diebold, such as by using the 12.2 micron thick Dupont Mylar film disclosed by Straus. A smaller spacer will create a smaller electrochemical cell effective volume, which is consistent with the purpose of Diebold: "A method for fabricating high-resolution, biocompatible electrodes is disclosed, allowing production of an electrochemical sensor which is capable of precise analyte concentration determination on a very small sample size. [emphasis added]"

As for the hollow electrochemical cell having an effective cell volume of less than 1.5 microliters, this is just a matter of scaling the spacer of Diebold. Diebold is directed to a small volume sensor and discloses a cell volume of 3 microns. See the abstract and col. 12:35-42. The spacer, by its thickness and the width of the capillary channel, defines the cell volume in Diebold. See Figure 5. It may be made of a plastic film, such as MYLAR™ film. See Figure 5 and col. 7:14-18 and col. 7:55-57. As noted above, at the time of the invention MYLAR™ film of only 12.2 microns in thickness was commercially available. Diebold also discloses using a laser to from a cutout that defines the capillary channel. See col. 7:14-21. Thus, barring evidence to the contrary, such as unexpected results, having an effective cell volume of less than 1.5 microliters is just a matter of scaling the cell volume in Diebold by using a thin enough spacer, such

as using the 12.2 micron thick Dupont Mylar film disclosed by Straus, and/or creating a narrow enough capillary channel by using thin enough laser beam.

Addressing claim 2, as discussed in the rejection of claim 1 Diebold discloses a carbon working electrode.

Addressing claims 3 and 4, Diebold states, "A working, counter, or reface electrode element may be produced in accordance with the present invention as shown in Fig. 1. Electrically conducting material **1** (e.g., a noble metal or carbon) is vacuum sputtered or evaporatively deposited onto thin support material **2** ..." [emphasis added]. See col. 3:50-54. So, barring evidence to the contrary, such as unexpected results, whether to use a noble metal for the counter electrode and a nonmetal for the working electrode is just a matter of optimizing the electrochemical cell (sensor), while minimizing cost.

Addressing claim 6, for the additional limitation of this claim see Figure 5 of Diebold.

13. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Diebold et al. (US 5,437,999) in view of Straus et al. (US 5,089,320) ("Straus") as applied to claims 1-4 and 6 above, and further in view of Carter et al. (US 5,126,034) ("Carter") and Bohs (US 5,399,256).

As for the metal being silver, since Diebold discloses that the metal may be a noble metal this is just optimization. In fact, Diebold discloses a counter electrode comprising silver (col. 12:43-55). Ag/AgCl was a common counter/reference electrode composition at the time of the invention. As shown by Carter and Bohs the combination of a non-metal (carbon) working electrode and a silver counter/ reference electrode is not novel. See Figure 1 and col. 2:28-48 in Carter and Figure 5; col. 2:62- col. 3:5;and col. 7:50-53 in Bohs.

As for chloride ions in the blood sample, the type of sample is intended use that does not appear to further structurally limit the electrochemical cell. In a nay event Diebold discloses directly measuring blood (col. 12: 35-42) and blood contains various chloride salts, such as NaCl or KCl.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alex Noguerola
Primary Examiner
AU 1753
June 13, 2005